

### § 63.143

procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(q) *Corrective action.* DOE shall establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. If significant conditions are adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(r) *Quality assurance records.* DOE shall maintain sufficient records to furnish evidence of activities affecting quality.

(1) The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

(2) The records must also include closely-related data such as qualifications of personnel, procedures, and equipment.

(3) Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

(4) Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(s) *Audits.* DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not

### 10 CFR Ch. I (1–1–04 Edition)

having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

#### § 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria required by § 63.142.

#### § 63.144 Quality assurance program change.

Changes to DOE's NRC-approved Safety Analysis Report quality assurance program description are processed as follows:

(a) DOE may change a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted every 24 months, in accordance with paragraph (b)(1) of this section. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the NRC which is more recent than the quality assurance standard in DOE's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text;

(4) The elimination of quality assurance program information that duplicates language in quality assurance

## Nuclear Regulatory Commission

§ 63.161

regulatory guides and quality assurance standards to which the licensee is committed; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(b) DOE shall submit changes made to the NRC-accepted Safety Analysis Report quality assurance program description that do reduce the commitments to the NRC and receive NRC approval prior to implementation, as follows:

(1) By an appropriate method listed in § 63.4 of this chapter, the signed document must be submitted to the Nuclear Regulatory Commission, addressed: ATTN: Document Control Desk; Director, Office of Nuclear Material and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and one copy to the appropriate NRC Resident Inspector, if one has been assigned to the site or facility.

(2) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to describe how the requirements of § 63.142 will be satisfied and continues to satisfy the criteria of § 63.142 and the Safety Analysis Report quality assurance program description previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(3) DOE shall maintain records of quality assurance program changes that do reduce commitments.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58816, Oct. 10, 2003]

## Subpart H—Training and Certification of Personnel

### § 63.151 General requirements.

Operations of systems and components that have been identified as important to safety in the Safety Analysis Report and in the license must be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who direct operations that are important to safety must also be certified in such operations.

### § 63.152 Training and certification program.

DOE shall establish a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.

### § 63.153 Physical requirements.

The physical condition and the general health of personnel certified for operations that are important to safety may not be such as might cause operational errors that could endanger the public health and safety. Any condition that might cause impaired judgment or motor coordination must be considered in the selection of personnel for activities that are important to safety. These conditions need not categorically disqualify a person, so long as appropriate provisions are made to accommodate the conditions.

## Subpart I—Emergency Planning Criteria

### § 63.161 Emergency plan for the geologic repository operations area through permanent closure.

DOE shall develop and be prepared to implement a plan to cope with radiological accidents that may occur at the geologic repository operations area, at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities. The emergency plan must be